UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/932,503	08/17/2001	Tulin Morcol	37070/207071	6972

23370 7590 08/04/2006

JOHN S. PRATT, ESQ
KILPATRICK STOCKTON, LLP
1100 PEACHTREE STREET
ATLANTA, GA 30309

EXAMINER	
ZEMAN, ROBERT A	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 08/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/932,503	MORCOL ET AL.	
	Examiner	Art Unit	
	Robert A. Zeman	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-18* is/are pending in the application.

4a) Of the above claim(s) *18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 2/8/06
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment and response filed on 5-24-2006 are acknowledged. Claim 12 has been amended. Claims 19-21 have been canceled. Claims 12-18 are pending. Claim 18 remains withdrawn from consideration as being drawn to a non-elected invention. Claims 12-17 are currently under examination.

Claim Rejections Withdrawn

The rejection of claims 12 and 17 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the recitation of the phrase " a layer of casein at least partially covering and forming a protective coating that encapsulates the core" is withdrawn in light of the amendment thereto.

Claim Rejections Maintained

35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 12-17 under 35 U.S.C. 103(a) as being unpatentable over Nuwayser (U.S. Patent 5,648,097 – IDS) and Corrigan et al. (WO 99/03451) is maintained for reasons of record.

Applicant argues:

1. There is no motivation to combine the Nuwayser particles with the casein of Corrigan because the Nuwayser patent specifically teaches, "it is a further object of the invention to develop novel mineral particles which are capable of degrading or eroding in a simple manner". This teaches away from coating the particles to prevent their erosion so they may be delivered orally.

2. There is no place in the disclosure by Nuwayser that would motivate one of ordinary skill in the art to seek out the casein of Corrigan and combine it with the Nuwayser particles.

3. The Examiner has failed to explain why the skilled artisan would attempt to deliver the Nuwayser particles orally.

Applicant's arguments have been fully considered and deemed non-persuasive.

The instant invention is drawn to a method of delivering a therapeutic amount of a therapeutic agent to a patient comprising orally delivery of one or more particles wherein said particles comprise a calcium phosphate core, a therapeutic agent associated with said core and a casein layer that at least partially covers said core.

With regard to Points 1 -3, Nuwayser specifically discloses that their microparticles can be coated with a biodegradable and/or bioerodible compound to alter degradation and the delivery profile of the active compound (see column 4, lines 19-23) and that their microparticles can be tailored to have different erosion lifetimes (see column 5, line 52 to column 6, line 4). Therefore, contrary to Applicant's assertion, Nuwayser does not teach away from the claimed invention. Moreover, since Nuwayser discloses that "biologically active agent" can be an antibiotic or a nutritional agent, the skilled artisan would look to modify the microparticles of Nuwayser since antibiotics and nutritional agents are traditionally administered orally. This would necessarily lead to the disclosure of Corrigan.

As outlined previously, Nuwayser discloses methods for adsorbing biologically active compounds to calcium phosphate particles wherein the resulting particles serve as controlled release drug delivery vehicles (see abstract, column 5 lines 16-36). Nuwayser further discloses that the biologically active agent or drug can be any drug or biologically active agents that can be released into an aqueous environment including peptide drugs, antibiotics anti-inflammatory agents, antivirals, etc. (see column 6, lines 5-23). Finally, Nuwayser discloses that the disclosed microparticles can be coated with a biodegradable and /or bioerodible compound in order to alter the delivery profile of the active ingredient (see column 4, lines 18-24).

Nuwayser differs from the claimed invention in that he does not explicitly disclose the use of casein as a coating substance, the use of polyethylene glycol as a surface modifying agent or the use of insulin as the biologically active agent.

Corrigan et al. disclose the use casein in pharmaceutical compositions to reduce the irritating effects of the active ingredient (therapeutic compound) [see page 5 lines 10-14] and to provide controlled release pharmaceutical compositions for oral administration (see page 6, lines 4-6). Corrigan et al. further disclose that casein can be used in conjunction with multiple formulation "forms" including granules (i.e. particles) [see page 7, lines 20-32].

Consequently, it would have been obvious for one of skill in the art to use the casein disclosed by Corrigan et al. in conjunction with the calcium phosphate particles disclosed by Nuwayser et al. in order to take advantage of the increased drug delivery associated with the use of casein and to provide controlled release pharmaceutical compositions for oral administration. Moreover, the skilled artisan would have been additionally motivated to combine the teachings of the aforementioned references in hopes of filling the need for alternative insulin delivery methodologies.

One of ordinary skill in the art would have had a reasonable expectation of success since Corrigan et al. disclose that casein can be used with "granular formulations" and Nuwayser discloses that his particles can be coated with a biodegradable and /or bioerodible compound in order to alter the delivery profile of the active ingredient. Consequently, the combination of the cited references renders all the rejected claims obvious.

It should be noted that while Nuwayser does not explicitly disclose the use of insulin as the biologically active agent, its use is deemed to be an obvious variation of the particles disclosed by Nuwayser since he discloses that the biologically active agent or drug can be any drug or biologically active agents that can be released into an aqueous environment.

Additionally, while Nuwayser does not explicitly disclose the use of polyethylene glycol as a surface-modifying agent its use is deemed obvious since Nuwayser discloses that the disclosed microparticles can be coated with a biodegradable and /or bioerodible compound in order to alter the degradation profile of the active ingredient (see column 4, lines 18-24).

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ROBERT A. ZEMAN
PRIMARY EXAMINER

August 2, 2006